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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 09/646,748 | 12/11/2000 | Julio Boza | 112701 036 | 7778 |
| 7590 | 06/03/2005 | | EXAMINER MOHAMED, ABDEL A | |
| Robert M Barrett P O Box 1135 Chicago, IL 60690-1135 | | | ART UNIT 1653 | PAPER NUMBER |
| DATE MAILED: 06/03/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,748

Applicant(s)

BOZA, JULIO

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/24/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

STATUS OF THE APPLICATION AND CLAIMS

1. Claims 1-16 are pending in the application. The allowance of claims 1-16 is vacated in view of the new ground of rejection as set forth below.

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballevre et al (U.S. Patent No. 5,849,335).

Claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestines (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7, wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further

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includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes carbohydrate source (claims 10, 13 and 16).

Balleve et al disclose a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-term infant or babies) as disclosed on the abstract; col. 1, lines 44-50; col. 3, lines 1-25; col. 6, lines 13-38; claims 24, 26-28 and 30. Thus, clearly meeting the limitations of claims 1-4.

On col. 4, the prior art discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 10% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain and long chain fatty acids, and as such meet the limitations of claims 5, 6, 8, 9, 11, 12, 14 and 15. The reference also discloses a nutritional composition which further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and as such meet the limitations of claim 10, 13 and 16 (See e.g., col. 2, lines 46-64; col. 4, lines 4-56 and Examples 2-4).

In regard to the percentages of the whey protein, the percentages claimed is inherent in the casein of milk which clearly reads on the limitation of **approximately** 80% to about 90% by weight of casein, and further overlaps with the disclosed amount of about 10 to 30% of mixtures of whey and casein because **approximately** is a relative term which encompass the recited ranges disclosed by the prior art. Thus, the reference clearly discloses the administration of nutritional composition, which contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for the same purposes (i.e., for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athletes). Therefore, as the whey protein hydrolysate comprises glutamine and it is used for nutritional purposes (i.e., a metabolic process), which is a mechanism wherein the sum total of chemical and physical processes within the body related to release of energy by the breakdown of chemical fuel and the use of that energy by the cells for their own work. Thus, clearly showing the known principles of physiology that naturally occurs after intake of food or meal that increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammal and provides treatment to patients suffering from injured, diseased or under-developed intestines.

With respect to the molecular weight of claim 7, the molecular weight is not disclosed in the prior art; however, the claim as drafted recites any hydrolysate whey protein having a molecular weight which is less than 1, 000 Da or having a molecular weight of 1,000 Da to 5,000 Da or a molecular weight greater than 5,000 Da; and does not define the molecular weight as functional limitation, rather, the claim defines the

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molecular weight as properties of the hydrolysate whey protein formulations. Thus, the hydrolysate whey protein formulations of the prior art would have the same molecular weight as claimed (i.e., less than 1,000 Da or greater than 5,000Da) because the claim does not identify specific protein(s) having a molecular weight greater than 5,000 Da, or fragments thereof having a molecular weight less than 1,000 Da, and as such, the molecular weight is an inherent properties of the prior art protein. Therefore, in the absence of evidence to the contrary, the nutritional formulation and its use thereof as disclosed by the reference anticipate claims 1-16 as drafted.

CONCLUSION AND FUTURE CORRESPONDANCE

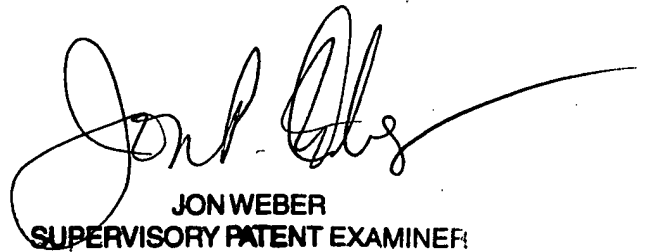
3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON WEBER
SUPERVISORY PATENT EXAMINER

AM Mohamed/AAM
May 31, 2005